

Remarks

The present invention as now claimed is directed to a drug delivery conformal film system adapted to be applied by medical personnel at the point of use, to an unexpandable implantable medical device such as pacemakers, vascular grafts, suture rings of mechanical heart valves, implantable injection or infusion ports, implantable drug delivery pumps, orthopedic hardware and appliances, and, neurological stimulating devices.

The current status of the claims is as follows:

1. Claims 1, 5-8, 12, 13 and 15 are rejected under 35 U.S.C. §102 (b) as being anticipated by Sahatjian et al.
2. Claims 1, 5-8, 12, 13 and 15 are rejected under 35 U.S.C. §102 (b) as being anticipated by Dayton.
3. Claims 2-4, 9-11, 14 and 16-20 are withdrawn from consideration.

The status of claim 16 seems to be uncertain. The Office Action Summary page lists claim 16 as being withdrawn from consideration while the Detailed Action at page 2, second paragraph, does not list claim 16 as being withdrawn. In looking at claim 16, Applicants respectfully do not understand why this claim should be withdrawn as it is not related to the species set forth by the Examiner is the restriction requirement.

The Examiner has rejected claims 1, 5-8, 12, 13 and 15 under 35 U.S.C. §102 (b) as being anticipated by Sahatjian et al. This rejection is respectfully traversed.

Sahatjian et al. teach an apparatus for drug delivery comprising an expandable portion which includes a stent (col. 2, line 28) having a polymer coating thereon and including a desired dosage of a drug incorporated in the polymer. The drug is released from the

polymer by expansion of the expandable portion which compresses the polymer thereby delivering the drug by squeezing the drug from the polymer. Note Sahatjian et al. at column 1, lines 62-67; column 2, lines 39-46; column 3, lines 25-27; column 5, lines 38-41; column 6, lines 12-13, 22, 38-39 and 46-47; and column 7, lines 6-8, among others.

With claim 1 as now amended, the medical devices are limited to those that are "unexpandable". Support for this amendment can be found at page 10, lines 9-10. Sahatjian et al. relies on an expandable device for delivery of a drug. Without such expansion, the invention will not function. The claims of the present invention, as currently amended, clearly recite that the device is unexpandable, thereby taking the claimed invention outside the realm of contemplation by Sahatjian et al.

Given the above, the rejection of claims 1, 5-8, 12, 13 and 15 as being anticipated by Sahatjian et al. is now believed to be moot and should be withdrawn.

The Examiner has also rejected claims 1, 5-8, 12, 13 and 15 under 35 U.S.C. §102 (b) as being anticipated by Dayton. This rejection is respectfully traversed.

Dayton at column 4, line 24-33, teaches an expandable stent having a polymer coating that contains a bioactive substance wherein the polymer coating is fabricated as a microporous structure where the pore size is selected to both control and prolong the release of the drug. Column 7, lines 1-7, and claim 1 (column 8, lines 20-25), again detail the pore size and the bioactive substance (drug or therapeutic agent) eluting from the pores. In contrast, with the present invention, the porosity of the polymer coating is not controlled. In fact, it is of no concern. Instead, the therapeutic agent is incorporated into the hydrogel matrix and delivered as the hydrogel biodegrades, bioabsorbs or bioerodes as is claimed in claim 1 of the present invention.

Furthermore, Dayton teaches coating of expandable stents. See column 4, lines 42-44. Expandable devices are now excluded by claim 1 and therefore Dayton cannot anticipate Applicants devices as are now claimed.

Given the above, the rejection of claims 1, 5-8, 12, 13 and 15 as being anticipated by Dayton is now believed to be moot and should be withdrawn.

Conclusion

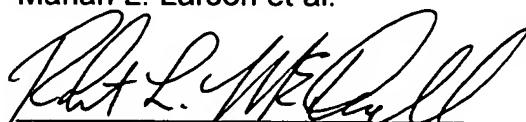
For the reasons set forth above, the rejection of claims 1, 5-8, 12, 13 and 15 as anticipated by Sahatjian et al. or Dayton is improper as the references each fail to recite an unexpandable implantable medical device having a film adhered thereto with the film comprising an in vivo biocompatible and biodegradable or bioabsorbable or bioerodable polymer, the film further comprising a desired dosage amount of one or more predetermined drugs. As such, withdrawal of the rejections is respectfully requested and the prompt issuance of a Notice of Allowance is earnestly solicited.

Having believed to have fully addressed all issues of the last Office Action, Applicants consider this response to be complete and timely in all respects. However, if the Examiner feels that there are issues yet outstanding, he is cordially invited to telephone Applicant's Agent at (585) 872-3857 to resolve such issues.

Respectfully submitted,

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by



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